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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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[REDACTED] EXAMINER

HAAS, WENDY C

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1661

DATE MAILED: 09/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|--------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/018,595 | AUBRY ET AL. |
| | Examiner Wendy C Haas | Art Unit 1661 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 05 June 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-5 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 05 June 2002 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) , Interview Summary (PTO-413) Paper No(s). _____ .
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____ .

DETAILED ACTION

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

(a) It does not state that the person making the oath or declaration believes the named inventor or inventors to be the original and first inventor or inventors of the subject matter which is claimed and for which a patent is sought.

(b) The specification to which the oath or declaration is directed has not been adequately identified. See MPEP § 601.01(a).

(c) It does not state that the person making the oath or declaration has reviewed and understands the contents of the specification, including the claims, as amended by any amendment specifically referred to in the oath or declaration.

(d) It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

Claim Objections

Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 5 sets forth and intended use of the method, and therefore fails to further limit the independent claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Dean.

Dean teaches an apparatus comprising a closed vessel, a biomass immobilization matrix positioned in the closed vessel, a liquid medium contained in the closed vessel with the level of same lower than the biomass immobilization matrix and spraying equipment for spraying medium onto the biomass immobilization matrix. See FIG. 1 which illustrates a coffeemaker that is a closed vessel with a filter (immobilization matrix) positioned in the vessel to hold coffee grounds (biomass), showing a sprayer above the coffee and filter that sprays liquid on to the ground coffee and a holding tank below to contain the liquid that drains through the coffee and filter.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Birdwell. Birdwell teaches an apparatus comprising a closed vessel, a biomass immobilization matrix positioned in the closed vessel, a liquid medium contained in a the closed vessel with the level of same lower than the biomass immobilization matrix, spraying equipment for spraying medium onto the biomass immobilization matrix and gas control equipment for controlling the concentration of oxygen in the gas phase of the closed vessel. See FIG. 1, which illustrates a biological purification system for polluted air. The system is contained in a closed vessel. In the

vessel is a “wet fill chamber” with “at least one spray nozzle located within” and the nozzle sprays liquid “laden with microbial agents” onto a filtration medium (biomass immobilization matrix). Liquid passes through the filtration medium and is collected in a “wet plenum chamber” beneath the “wet fill chamber”. See Column 2, lines 31-47. Birdwell also discloses gas control equipment for controlling the concentration of oxygen, see e.g. Column 2, lines 12-13 and Column 2, lines 60-62.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Endo et al. Endo et al. teach an apparatus comprising a closed vessel, a biomass immobilization matrix positioned in the closed vessel, a liquid medium contained in a the closed vessel with the level of same lower than the biomass immobilization matrix, spraying equipment for spraying medium onto the biomass immobilization matrix and gas control equipment for controlling the concentration of oxygen in the gas phase of the closed vessel. See, FIG. 2, which shows a closed vessel with a porous substrate designed to hold biomass and a level of liquid medium below it. Also disclosed are supply pipes for supplying sterilized . . . air. Col. 3, lines 59-60, and an inoculation nozzle (sprayer) (Col. 4, line 9).

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by O’Brien et al. O’Brien et al. teach an apparatus comprising a closed vessel, a biomass immobilization matrix positioned in the closed vessel, a liquid medium contained in a the closed vessel with the level of same lower than the biomass immobilization matrix, spraying equipment for spraying medium onto the biomass immobilization matrix and gas control equipment for controlling the

concentration of oxygen in the gas phase of the closed vessel. See FIG. 2 which discloses a closed vessel with a biomass immobilization matrix (28) held above a liquid medium (30) and a sprayer above that (34) along with means for controlling oxygen (36) (38).

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Weathers et al. ('464). Weathers et al. ('464) teach an apparatus comprising a closed vessel, a biomass immobilization matrix positioned in the closed vessel, a liquid medium contained in a the closed vessel with the level of same lower than the biomass immobilization matrix, spraying equipment for spraying medium onto the biomass immobilization matrix and gas control equipment for controlling the concentration of oxygen in the gas phase of the closed vessel. See FIG. 5. The apparatus comprises a sealable growth chamber (Col. 3, lines 60-61) containing “[a] screen of biologically inert material [which] has a mesh or pore size which supports cells while enabling good drainage.” (biomass immobilization matrix) The apparatus further comprises a misting device (Col. 4, lines 15-16) and “[a] filtered gas outlet” (Col. 4, lines 24-25.)

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Weather et al (In Vitro). Weathers et al. (In Vitro) teach an apparatus comprising a closed vessel, a biomass immobilization matrix positioned in the closed vessel, a liquid medium contained in a the closed vessel with the level of same lower than the biomass immobilization matrix, spraying equipment for spraying medium onto the biomass immobilization matrix and gas control equipment for controlling the concentration of oxygen in the gas phase of the closed vessel. The Summary notes “A nutrient mist was used for *in vitro* culture of plant tissue in a novel bioreactor wherein

the tissues were grown on a biologically inert screen within a sterile chamber which allows excess media to drain away..." The invention further comprises a sprayer (see FIG. 1 and 2nd paragraph of 2nd column on page 728) and means to produce positive air pressure (i.e. oxygen control) (see top of 1st column on pg. 729.)

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Dilorio et al. Dilorio et al. teach an apparatus comprising a closed vessel, a biomass immobilization matrix positioned in the closed vessel, a liquid medium contained in a the closed vessel with the level of same lower than the biomass immobilization matrix, spraying equipment for spraying medium onto the biomass immobilization matrix and gas control equipment for controlling the concentration of oxygen in the gas phase of the closed vessel. See Fig. 1, Fig. 2, and "*Bioreactor configuration*" on page 458.

Claims 1 -4 are rejected under 35 U.S.C. 102(b) as being anticipated by Weathers et al. ('928). Weathers et al. ('928) teach an apparatus comprising a closed vessel, a biomass immobilization matrix positioned in the closed vessel, a liquid medium contained in a the closed vessel with the level of same lower than the biomass immobilization matrix, spraying equipment for spraying medium onto the biomass immobilization matrix and gas control equipment for controlling the concentration of oxygen in the gas phase of the closed vessel, as well as a bioreactor culture process comprising the steps of installing a biomass immobilization matrix in a closed vessel, sterilizing the biomass immobilization matrix and the closed vessel, introducing a liquid culture medium in the closed vessel to immerse the biomass immobilization matrix,

adding a given volume of cultured cells in the liquid culture medium, immobilizing the cultured cells onto the biomass immobilization matrix, reducing the level of liquid culture medium to a level lower than the biomass immobilization matrix, spraying liquid culture medium onto the biomass immobilization matrix and controlling the concentration of oxygen in the gas phase of the closed vessel. Specifically, a culture chamber is supplied with an ultrasonic transducer to provide mist (Col. 12, lines 54-57) and a vent to control oxygen (Col. 13, line 34). The chamber has 3 levels of nylon mesh to hold the biomass being cultured. Medium can drain through this mesh (see Col. 14, lines 24-25 and Col. 4-5 lines 64-5.) The closed vessel culture chamber was sterilized before adding biomass (see Col. 13, lines 64-65 “sterile nutrient media from the sump at the bottom of the culture chamber,” “sterile and loaded with tissue” Col. 13, lines 21-22.) The ‘928 patent discloses flooding the culture chamber with liquid medium to “just above the tissue in the nylon matrix”, and then draining that liquid medium and culturing the tissue in the vessel with mist. (Col. 13, lines 35-48.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weathers et al. (‘928) as applied to claims 1-4 above, and further in view of Timmis et al. The teachings of Weathers et al. are set forth above. Weathers et al. do not teach a bioreactor culture process for

producing somatic embryos of conifer species. Timmis et al. teach a bioreactor culture process for producing conifer somatic embryos comprising installing a biomass immobilization matrix in a closed vessel, sterilizing the biomass immobilization matrix and the closed vessel, introducing a liquid culture medium in the closed vessel to immerse the biomass immobilization matrix immobilizing a given volume of cultured cells on the biomass immobilization matrix and reducing the level of liquid medium to a level lower than the biomass immobilization matrix where the cultured cells are conifer somatic embryos. (See Example 1.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Weathers et al. ('928) to apply to conifer somatic embryos, or alternately to modify the method of Timmis et al. to include a sprayer because conifers may be economically important for secondary metabolite production and, as noted in Weathers et al. (*In Vitro*) "[a]ll plants grew at least as well in nutrient mists as in agar and always produced a greater quantity of shoots of a higher quality and often faster than agar cultures. As Timmis et al. teach that their method is applicable to a variety of conifer species, one of ordinary skill in the art would have an expectation of success in applying the method of Weathers et al. ('928) to conifer species. Greater yield of an economically important plant in less time, especially alongside an expectation of success, is a powerful motivation to combine known useful trends in bioreactor cell production. Thus, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claim is allowed.

Future Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Wendy C. Haas whose telephone number is (703) 308-8898. The Examiner is normally available Monday through Friday from 9:00 a.m. to 5:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Bruce Campell, can be reached on (703) 308-4205. The fax number for the group is (703) 872-9306 for regular communications and (703) 872-9307 for After-Final communications.

Any inquiry of a general nature or relating to the status of this application should be directed to the Matrix Customer Service Center whose telephone number is (703) 872-9305.

W.C. Haas



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